REMARKS

Claims 1-20, 37-41, 45 and 46 are currently pending in the application. Claim 21 is cancelled without prejudice regarding its subject matter. Applicant respectfully submits that upon entry of this Amendment the application will be in condition for allowance, as discussed in detail below. Thus, prompt and favorable consideration of this amendment is respectfully requested.

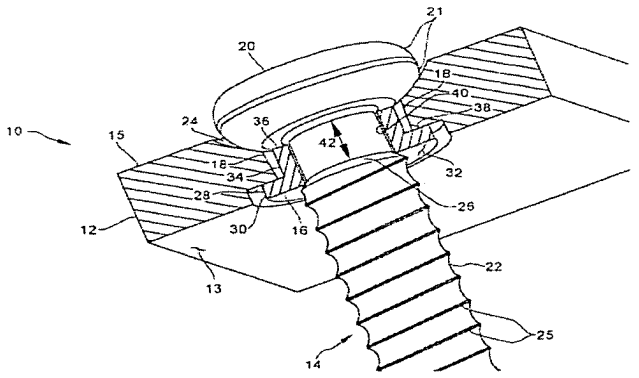
REJECTION UNDER 35 U.S.C. § 103

Claims 1-6, 8, 9, 11, 12, 15-21, 37-41, 45, and 46 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Estes (U.S. Pat. No. 5,578,034) in view of Ishida (U.S. Pat. No. 5,158,409). This rejection is respectfully traversed.

Claim 21 is canceled without prejudice.

Estes discloses merely a fixation plate with a modular fastener including a collar and a shaft. The Office Action provides a long list of what Estes does not disclose starting midway on p. 4 of the Office Action and ending at the top of p. 7. In addition, Estes fails to disclose that a modular fixation fastener having an expandable head and a shaft that can be positioned at a plurality of angles relative to the plate before locking through articulation of the expandable head member relative to the fixation hole. In fact, the annular ring 16 and fastening element 14 of Estes can only provide a fattener that can rotate about its own axis, but cannot be positioned at a plurality of angles relative to the plate, i.e., it cannot angulate, because the relative geometries of the plate, ring, head 20 and fastening element 14. See FIG. 1. Further, the ring 16 is made of shape

memory material and expands by change in temperature and not by rotation relative to the fastening element. See column 6, lines 47-55.



Estes, FIG. 1

Ishida discloses a bolt lock. The relevant embodiment of Ishida is illustrated in FIGS. 33-35. From FIG. 33 and the scant description provided in column 8, lines 63-64, and column 9, lines 1-2 and 12-13, it may be surmised that the inner member 1c has an outer cam that is tri-lobed and the inner surface of the split ring 209 is also tri-lobed. However, both of these surfaces are cylindrical and do not permit angulation, nor is angulation desirable. See related FIGS. 34 and 35.

Fig.33

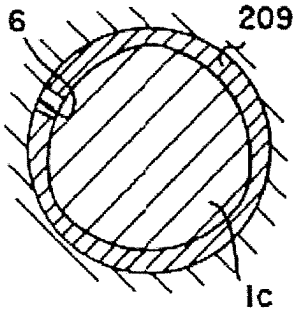


Fig.34

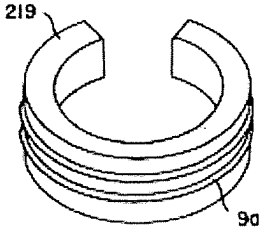
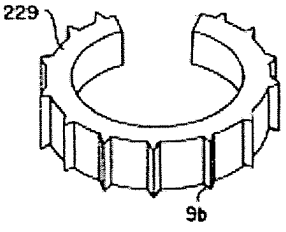


Fig.35



Ishida

Accordingly, neither Estes nor Ishida, individually or in combination, disclose a modular fastener that can be positioned at an adjustable angle relative to the plate in one position or mode operation.

More specifically, Estes and Ishida, even if combinable, fail to disclose all the limitations of the currently pending independent claims 1, 17, 37, and 45. For example, regarding claim 1, the combination fails to disclose, among other things and in the context of the other limitations recited in claim 1, a modular fixation fastener that is adjustably angled relative to the plate through articulation of the expandable head member relative to the fixation hole in the unexpanded configuration of the expandable head member.

Similarly, and regarding independent claim 17, the combination fails to disclose, among other things and in the context of the other limitations recited in claim 17, a modular fixation fastener that is positionable at a plurality of angles relative to the fixation plate through articulation of the expandable head member relative to the fixation hole when the head member is unexpanded.

Regarding independent claim 37, the combination fails to disclose, among other things and in the context of the other limitations recited in claim 37, a modular fixation fastener wherein the head member and the shaft member of the fastener are cooperatively configured to provide a first mode of operation in which the head member is prevented from backing out relative to the plate and the fixation fastener is adjustably angled relative to the plate through articulation of the expandable head member relative to the fixation hole, and a second mode of operation in which the head member is

prevented from backing out relative to the plate and the fixation fastener is locked at a fixed angle relative to the plate.

Regarding independent claim 45, the combination fails to disclose, among other things and in the context of the other limitations recited in claim 45, a modular fixation fastener that is adjustably angled relative to the plate through articulation of the expandable head member relative to the fixation hole in the unexpanded configuration of the expandable head member.

Therefore, independent claims 1, 17, 37, and 45 are patentable over Estes in view of Ishida. Claim 21 is canceled without prejudice. Claims 2-6, 8, 9, 11, 12, 15, and 16 ultimately depend from claim 1; claims 18-20 ultimately depend from claim 17; claims 38-41 ultimately depend from claim 37; and 46 depends from claim 45. At least for this reason, as well as for their own limitations, claims 2-6, 8,9, 10, 11, 15, 16, 18-20, 38-41 and 46, are also patentable over Estes in view of Ishida.

Further, Applicants disagree that the person of ordinary skill in the art (PHOSITA) of bone fixation, typically an orthopedics engineer or surgeon, would be motivated to consider the non-analogous art of bolts and locks, especially when such art does not relate to the problem of preventing backing out and providing adjustable orientation screws. Further, even if such combination was considered by the PHOSITA, the combination would not produce the claimed invention without impermissible hindsight of the Applicants' inventive steps.

Claims 7 and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Estes in view of Ishida in view of Eisermann (U.S. Pat. No. 6,342,055). This rejection is respectfully traversed.

Claims 7 and 10 ultimately depend from independent claim 1, which, as discussed above, is patentable over Estes in view of Ishida. The Office Action cites Eisermann for the element of the viewing window. Eisermann does not add any of the above-identified elements missing from independent claim 1.

Claims 13 and 14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Estes in view of Ishida and further in view of Bailey et al (U.S. Pat. No. 6,599,290). This rejection is respectfully traversed.

Claims 13 and 14 ultimately depend from independent claim 1, which, as discussed above, is patentable over Estes in view of Ishida. The Office Action cites Bailey et al for the element of the insertion and removal tool. Bailey et al does not add any of the above-identified elements missing from independent claim 1.

Accordingly, reconsideration and withdrawal of the above rejections is respectfully requested.

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner

believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

Dated: October 25, 2007

By: _____

Maria Comninou
Reg. No. 44,626
Stephen T. Olson
Reg. No. 36,626

HARNESS, DICKEY & PIERCE, P.L.C.
P.O. Box 828
Bloomfield Hills, Michigan 48303
(248) 641-1600

STO/MC/sms